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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,813	01/03/2002	Lawrence M. Boyd	4002-2734	1340
52196 7590 02/26/2007 KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER COMSTOCK, DAVID C	
			ART UNIT 3733	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/869,813

Applicant(s)

BOYD ET AL.

Examiner

David Comstock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,17,18,20,34-37,46,47,50-52,54,56 and 59-82 is/are pending in the application.
- 4a) Of the above claim(s) 46,47,50,51 and 76-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11,13-15,17,18,20,34-37,52,54,56,59,61-64,66-69 and 72-75 is/are rejected.
- 7) ☒ Claim(s) 12,60,65,70 and 71 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 28 November 2005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Invention Group I, corresponding to claims 1, 2, 5-15, 17, 18, 20, 34-37, 52, 54, 56 and 59-75, in the reply filed on 04 December 2006 is acknowledged. Because applicant did not distinctly and specifically point out any supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 46, 47, 50, 51 and 76-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-7, 9-11, 13, 18, 20, 34, 52, 54, 56, 59, 62-64, 68 and 73-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Zdeblick et al. (5,669,909; previously cited).

Zdeblick et al. disclose a pair of interbody fusion devices 10 comprising an elongated generally cylindrical body having end walls 12 and 17, a side wall 16, and a hollow interior chamber 15 between the two ends (Fig. 2). One end 12 has flat

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discontinuities corresponding to discontinuities 22 in the side wall. The discontinuities allow the device to be nested against another device in a single disc space (see Fig. 6 and col. 7, lines 50-58). The side wall discontinuity extends along a length of the body aligned with the end wall discontinuity. The side wall discontinuity defines a plurality of side wall openings 24,25 to the interior chamber 15. The interbody fusion device 10 is formed of metal (see col. 5, lines 42-47). The outer surface defines threaded bone-engaging portions 18. The device includes a tool-engaging end 13 defining a tool engaging hole, e.g. a hex recess (see col. 7, lines 6-10). An osteogenic material is disposed within the chamber (see col. 5, lines 55-59 and col. 7, lines 50-58). Each side wall discontinuity appears to extend over approximately 25% of the circumference of the body (see Attachment A, corresponding to Fig. 4). The side wall discontinuity appears to extend over at least 50% of the length of the body (see Fig. 2). Osteogenic material could be introduced through the openings 24,25. Zdeblick also discloses preparing adjacent vertebrae and placing the devices in the intervertebral space to nest against each other (see col. 7; lines 50-58 and col. 10, line 48 - col. 11, line 51 and Fig. 6). It is also disclosed to pack osteogenic material prior to or after implanting the devices, i.e. "additional bone graft material" where "additional" implies some was added before implantation while the "additional" amount was added "in situ" (see col. 5, lines 55-59 and col. 7, lines 50-58).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 14, 15, 17, 35-37, 61, 66, 67, 69 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (5,669,909; previously cited) in view of Michelson (5,593,409; cited by applicant).

Zdeblick discloses the claimed invention except for the concave side wall and end wall discontinuities. Michelson discloses that flat side walls and concave side walls are functionally equivalent means of allowing two implants to fit within a single disc space (see Figs. 25 and 43, col. 12, line 59 - col. 13, line 3; and col. 15, lines 19-38). It would have been obvious to substitute concave side wall discontinuities for flat side wall discontinuities, in view of Michelson, as this would involve nothing more than the substitution of functionally equivalent means of accommodating two implants in a single disc space, known in the art at the time of the invention. With regard to claim 8, it also would have been obvious to form the osteogenic material of demineralized bone, a calcium phosphate, bioceramic, bioglass, an osteoinductive factor, or other known materials or mixtures thereof, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

Claims 12, 60, 65, 70 and 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The openings in Zdeblick et al. extend at least 50% of the length but not as much as 80% and Applicant's argument that the reference would teach against this amount, for reasons pertaining to the strength of the implant, are persuasive. Moreover, though both Zdeblick et al. and Michelson have end caps, they are not non-removable.

Response to Arguments

Applicant's arguments filed 20 November 2005 have been fully considered but are not entirely persuasive.

As an initial matter, it is noted that Applicant's arguments, pertaining to the claims amended to overcome Brosnahan, III, are persuasive; accordingly, this rejection has not been maintained.

Applicant's argument that the end covering means of Zdeblick et al. and Michelson are not integral is not persuasive. When the end covering means is placed on the implant (after the bone graft material has been loaded into the implant), the assembly can be considered to be integral, at least in function, since the parts would act together as one. In order for the end covering means to be able to retain the bone graft material at all, the end covering means must be at least minimally attached or connected to the implant. It is noted that in a claim drawn to an apparatus, the process

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by which the claimed product is formed (i.e. "integrally formed") is not given patentable weight. Instead, the end result must be capable of being considered "integral" as it would be here.

It is also noted that both devices disclose what can be considered "threaded" outer surfaces that resist expulsion. "Threads" can encompass the structure shown in both references since a thread need not necessarily be helically wound (for example, interference threads or cross-threads).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-

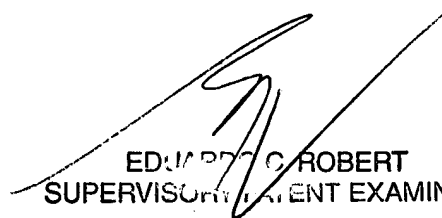
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4710. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



EDWARD C. ROBERT
SUPERVISORY PATENT EXAMINER